

## **REMARKS**

Applicants appreciate the courtesies extended to their representatives, Allan A. Fanucci and Teresa Chen, by Examiner David M. Naff during a telephone interview on January 8, 2008. The current rejections were discussed along with a proposed amendment. The Examiner agreed that the proposed amendment addressed the differences between the dried pellet preparations recited in the prior art and the porous cellular hydrocolloid carriers of the present invention, but deemed additional specification necessary. Accordingly, Applicants have now prepared new, further amended claims that should address the Examiner's concerns and define the invention in a patentable manner. The applicants detailed reasoning follows.

Claims 1, 7-8, 10-16, 18-20, and 43, as amended, and new claim 45 appear in this application for the Examiner's active review and consideration. Claim 1 has been amended to incorporate features of claims 2, 5, 9 and 21, which haven been cancelled. Claim 43 has been amended for clarity. New claim 45 is the combination of claims 1 and 19 and includes the preamble "consisting essentially of". Claim 44 has been cancelled. New claims 46-48 are directed to further embodiments that are recited in currently withdrawn claims 22, 31 and 36. As no new matter is introduce by these changes or additions, they all should be entered at this time.

Claims 22-40 and new claims 46-48 are withdrawn at this time. However, it is understood that they will be rejoined and allowed when claims 1 and 45, from which they ultimately depend, are allowed.

Claim 44 is objected to for informalities. As claim 44 has been cancelled, the objection is thus rendered moot and should be withdrawn.

Claims 1, 2, 5, 7-16, 18-21, 43 and 44 are rejected under 35 U.S.C. first paragraph, as failing comply with the written description requirement. In response, claim 43 has been amended to recite "bead wall thickness", which is supported in the specification as acknowledged by the Examiner. Claim 1 has been amended to delete the claim language objected to. Additionally, claims 2, 5, 9, 21 and 44 have been cancelled. Thus, the rejection is overcome and should be withdrawn.

Claims 43 and 44 are rejected under 35 U.S.C. 112, second paragraph, for being indefinite. As explained above, claim 43 has been amended for clarity and claim 44 has been cancelled. Thus, the rejection is overcome and should be withdrawn.

Claims 1, 2, 5, 7-13, 16, 18-21, 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,818,530 to Marois et al (referred to hereafter as "Marois") in view of U.S. Patent No. 4,956,295 to Sudoma (referred to hereafter as "Sudoma") and US patent No. 4,879,239 to Daggett et al. (referred to hereafter as "Daggett"), optionally in further view of US Patent No. 5,919,695 to Vedamuthu et al. (referred to hereafter as "Vedamuthu").

Before discussing the cited references, Applicants wish to emphasize that the present invention is based on the unexpectedly high viability of bacteria (and/or other microorganisms) that are entrapped within hydrocolloid beads that are subsequently freeze dried. The freeze dried hydrocolloid beads, especially with high percentages of a cryoprotectant (e.g., glycerol) as defined in claims 1 and 45, maintain the viability of the overwhelming majority of the entrapped microorganisms within these uniquely highly porous structures that are created by the freeze drying (lyophilization) process. Furthermore, claim 45 recites that the beads include nutrients or fillers selected from the group consisting of chitin, pectin, cellulose, lignin, bentonite, kaolin, starch, glycerol and lowfat milk in an amount sufficient to control the porosity of the beads. None of the cited references teaches or suggested the present invention.

Marois teaches pelletization of fungal spores for use in biocontrol and discloses that pelletization of the alginate requires calcium salt and gelation proceeds faster as the concentration of the salt solution is increased. Sudoma teaches the stabilization of dried bacteria in particulate carriers. Daggett teaches a preparation of freeze-dried microorganisms and the method for preparing thereof. Vedamuthu teaches an atypical *Bacillus subtilis* strain used in controlling molds and other spoilage flora in various materials.

In particular, Marois uses techniques for entrapping the microorganisms in hydrocolloid gels (alginate) but speaks explicitly of them being transformed into hard granules of pellets (column 5 lines 15-20) upon drying. The Examiner is correct that Marois does teach drying. However, Marois seeks a completely different solution to drying which provided a completely different result. Specifically, the reported results of Marois for viability are fine during formation of the pellets but very poor after storage such that the majority of the preparations lost 50% of the viability in a number of weeks (see Column ES<sub>50</sub> of Table 1 of Marois). In contrast, the freeze dried beads of the present invention maintains more than 50% viability after more than 12 months. Thus, the preparation disclosed in Marois is explicitly and self evidently inferior to that of the present invention.

Moreover, the disclosure in Sudoma, Daggett and Vedamuthu regarding the function of glycerol as a cryopreservative for freeze drying of bacteria is well known in the art. Furthermore, Sudoma discloses freeze drying of the bacteria BEFORE mixing with the inorganic salts to obtain highly diluted admixtures. In contrast, the freeze drying of the bacteria in the present invention occurs after the mixture has been prepared.

Thus, without teaching or suggesting that freeze drying bacteria within gels would improve the outcome of the prior art gels, these references fail to remedy the deficiencies of Marois, as one of skill in the art combining Marois with the other references could only arrive at dried microorganisms in the form of hard granules or pellets entrapped within a hydrocolloid gel, instead of a freeze dried porous hydrocolloid gel containing viable microorganisms which greatly enhanced the viability of the microorganisms upon freeze drying, as taught and claimed in the present invention.

Claims 14 and 15 are rejected under 35 U.S.C. §103(a) as being unpatentable over the above references and further in view of U.S. Patent No. 5,030,562 to Elliott et al. (referred to hereafter as "Elliott") or U.S. Patent No. 4,764,371 to Pusey et al. (referred to hereafter as "Pusey"). Elliott teaches a method of screening for bacterial strains which can inhibit the growth and spread of a species of weed that compete with crops while Pusey teaches post harvest control of brown rot on stone fruit.

As explained previously, the above cited references do not teach the porous freeze-dried beads of the present invention. Neither Elliott nor Pusey remedies this deficiency. Thus, Elliott and Pusey would not have any bearing on this application, whether the pellets contained bacteria or fungi.

Moreover, in Pusey, the test bacteria are directly applied to the surface of the fruit and, therefore, Pusey teaches away from applying the bacteria to the soil or plants (see col. 2, lines 41-51). Thus, it is unlikely that a skilled artisan would even be motivated to combine Marois and Pusey to obtain the invention defined by claims 14-15.

In summary, it is completely unfounded to assert that the outcome of freeze drying of hydrocolloid gel beads containing microorganisms with cryoprotectants would inherently have given the present results, since such a combination to provide a desired porosity was never sought in the prior art. There is no teaching or suggestion in the art that predicts that freeze drying of gels with microorganisms and a cryoprotectant would give porous gels which provide a

very high level of viable microorganisms over prolonged periods of storage in the frozen state (a period of years).

Therefore, none of the cited references, alone or in combination, teaches solid porous cellular hydrocolloid carriers including freeze-dried hydrocolloid beads comprising viable microorganisms entrapped therein. Thus, the obviousness rejection of claims 14-15 under 35 U.S.C. § 103(a) should be withdrawn.

In view of the above, it is respectfully submitted that all current rejections have been overcome and should be withdrawn. Accordingly, the entire application is believed to be in condition for allowance, early notice of which would be appreciated. Should the Examiner not agree, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of this application.

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Respectfully submitted,

  
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